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Message Text

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PAGE 01 STATE 070519
ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06
COME-00 EB-08 MED-03 /065 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
ARA/EX:RSGERSHENSON(INFO)
EA/EX:EECHAMPAGNE(INFO)
NEA/EX:JSCONNOLLY(INFO)
----------311439Z 095540 /41
P 302254Z MAR 77
FM SECSTATE WASHDC
TO AMEMBASSY NASSAU PRIORITY
AMCONSUL SAO PAULO PRIORITY
AMEMBASSY SANTIAGO PRIORITY
AMEMBASSY GUATEMALA PRIORITY
AMEMBASSY NEW DELHI PRIORITY
AMEMBASSY TEHRAN PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY MEXICO PRIORITY
AMEMBASSY ISLAMABAD PRIORITY
AMEMBASSY DAMASCUS PRIORITY
AMEMBASSY BANGKOK PRIORITY
AMEMBASSY ANKARA PRIORITY
AMEMBASSY CARACAS PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, BF, BR, CI, GQ, GT,
IN, IR, IS, KS, MX, PK, SY, TH, TU, VE

SUBJECT: FDA ADVISORY-LEAKAGE OF A-V FISTULA CANNUL-
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ATION (NEEDLE) ASSEMBLIES - RECALL T-014/015-7

1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE RECALL:

PRODUCTS INVOLVED:

(A) RECALL T-014-7 - ARTERIOVENOUS FISTULA CANNULATION

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SET WITH 15 GUAGE, 1 AND 1/4 INCH (3.2 CM) NEEDLE WITH STABILIZATION WINGS AND "Y" INJECTION SITE. CATALOG NUMBER 5M0271, LOT NUMBERS H217F8 UP TO AND INCLUDING H233H6.

(B) RECALL T-015-7 - ARTERIOVENOUS FISTULA CANNULATION SET WITH 15 GUAGE, 1 AND 1/4 INCH (3.2 CM) NEEDLE WITH STABILIZATION WINGS. CATALOG NUMBER 5M0272, LOT NUMBERS H211L4 UP TO AND INCLUDING H234HO.

MANUFACTURER: TRAVENOL LABORATORIES, INC., ARTIFICIAL ORGANO DIVISION, HIGHWAY 201 MOUNTAIN HOME, ARKANSAS 72633.

RECALLING FIRM: TRAVENOL LABORATORIES, INC., ARTIFICIAL ORGANS DIVISION, ONE BAXTER PARKWAY, DEERFIELD, ILLINOIS 60015.

2. REASON FOR RECALL:

LEAKAGE HAS OCCURRED AT THE ASSEMBLY AREA BETWEEN NEEDLE AND TUBING WHICH ARE CONNECTED BY A VINYL BUSHING.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER DATED 5 NOVEMBER 1976. LETTER INDICATES THAT PROBLEM COMMENCED SINCE MARCH 1976. FIRM REQUESTED RETURN OF ENCLOSED POST CARD INDICATING NUMBER OF SETS ON HAND AND ESTIMATE OF WEEKLY USAGE. UPON RECEIPT OF CARD TRAVENOL WILL ARRANGE FOR REPLACEMENT. FIRM STATES SETS ON HAND MAY BE USED PROVIDED CAUTION IS TAKEN PERIODICALLY TO INSPECT NEEDLE
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ASSEMBLY DURING DIALYSIS PROCEDURE. IF BLOOD FILMING BETWEEN SEALED JOINTS IN POSITIVE PRESSURE PORTION OF SYSTEM OR AIR BUBBLES STREAM INTO BLOOD STREAM IN NEGATIVE PRESSURE PORTION OF SYSTEM, SET IS TO BE REMOVED. WHEN REPLACEMENT SETS ARE PROVIDED FIRM REQUESTS RETURN OF ANY SETS FROM DESIGNATED LOTS. FIRM CONTACT IS SALES SERVICE DEPARTMENT (312)-948-2355 (COLLECT).

4. FOREIGN CONSIGNEES AS FOLLOWS:

GOVERNMENT OF THE BAHAMA ISLANDS
PRINCESS MARGARET HOSPITAL
P O BOX 3729
NASSAU, BAHAMAS

TRAVENOL PRODUCTS HOSPITAL
LTCA
RUA INFAMBU 1091-MOEMA
CEP 04520 SAO PAULO

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MAURICIO GATTAS BARA RUA
SANTO ANTONIO
1005 APT 502
JUIZ DE FORA MG BRAZIL

PCZO VICTOR HORMAZBAL
EXECUIFL FIGUEROA 896
SANTIAGO, CHILE

LAGARRIQUE, MARIA TERESA LIRA
OTCNAL
SANTIAGO, CHILE

ALBERTO BECK BOELITZ CAPITAL ARMED FORCES HOSP
LOS LECNES 2006 DEUNG CHEN DENG
SANTIAGO, CHILE YOUNG DELAG PC KL
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SEOUL, KOREA
ARANA, ANDRES VILLASANTE
MERCED 280 DEPTO 70 AP POSTAL 13-279
SANTIAGO, CHILE MEXICO 13 CF MEXICO

CASTOR CIFUENTES PIEGUEZ SOCIAL WELFARE ORGANIZATION
ISABEL LA CATOLICA 6040 CHMN CC-COORDINATING COM-
SANTIAGO, CHILE MITTEE
RAWAL PINDI
PAKISTAN

RODOLEC SEPLLVEDA CAPRASCU PAKISTAN
ANTONIO VARAS
SANTIAGO CHILE HOSPITAL MOUSSAH
DAMASCUS SYRIA
CLUB DE LEONES
DE TEMUCO SAWAH COMPANY
ROCHESTER 890 PLACE AZME BP 2308
TEMUCO, CHILE DAMASCUS SYRIA

LEONARDO F. CONTRERAS CESCO L.T.D.
JOERE 029 DEPTO 43 100-104 MANSION
SANTIAGO, CHILE RAJADAMNER VEAVE
P O BOX 445
BANGKOK THAILAND

INST GUATEMALTECO D SS
7A AV AND 220 ZONAT
GUATEMALA CITY GUATEMALA TIRSAN LTD
KARANFIL SOKAK 30/6
MEDICAL RESEARCH CENTRE OF ANKARA, TURKEY

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BOMBAY HOSPITAL TRUST
12 MARINE LINES LABORATORIOS BAXTER CA
BOMBAY 20 INDIA APDC 88739 ZONA 106
CARACAS, VENEZUELA

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SA ID TABIBI AND CC
P O BOX 14/1551
TEHRAN, IRAN

TRAV TRADING CO LTD
ASHDOD ISRAEL

YUN SAI UNIVERSITY
SEOUL, KOREA
CHRISTOPHER

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NNN

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Sent Date: 30-Mar-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE070519
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770110-0876
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977035/aaaaaels.tel
Line Count: 191
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: d51f7db6-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 20-Sep-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3080288
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-LEAKAGE OF A-V FISTULA CANNUL- UNCLASSIFIED UNCLASSIFIED
TAGS: OGEN, ETRD, EIND, TBIO, BF, BR, CI, GQ, GT
To: NASSAU SAO PAULO MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/d51f7db6-c288-dd11-92da-001cc4696bcc
Review Markings:
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